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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,356	03/31/2004	Mark S. Zeiner	END5008USCIP2	8274
27777 7590 03/15/2010 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER YABUT, DIANE D	
			ART UNIT 3734	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/815,356	Applicant(s) ZEINER ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-11,17,19,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-11,17,19,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 11/30/2009.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 6, 8-11, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Haber et al.** (U.S. Patent No. **5,385,552**) in view of **Honkanen et al.** (U.S. Patent No. **4,655,752**).

Claims 1, 6, and 8-9: Haber et al. disclose a trocar **2** with a hollow cannula **32** having a distal end and proximal end and a valve housing **58** attached to the proximal end of the cannula, wherein the proximal end has a wall attached thereto having an aperture therethrough, and an instrument seal assembly **122** disposed within said housing comprising a first substantially rigid ring **132**, and a second substantially rigid ring **134** and a plurality of layered elastomeric members, or four separate semicircular seal segments **126**, compressed therebetween, each having a circumference of 180 degrees, and arranged circumferentially about an aperture in an alternating over and under pattern in a non-planar shape (the elastomeric members also have a non-planar shape prior to being assembled together), and circumscribing an aperture in an

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interwoven pattern and cooperating to seal against objects positioned within the aperture, and each seal segment has a starting edge facing in the same circumferential direction and an ending edge facing in the opposite circumferential direction wherein the starting edge of each seal segment overlaps and is positioned on top of the ending edge of the adjacent seal segment, and the seal segments cooperate to seal against objects or instruments positioned within the aperture (Figures 2 and 5A).

Haber et al. do not expressly disclose each seal segment **126** being gas-tight or sufficiently sealing against instruments positioned through the seal to maintain gas pressure in the abdominal cavity during endoscopic surgical procedures, however discloses having good sealing qualities (col. 2, lines 11-44). It would have occurred to one of ordinary skill in the art to form a seal tight enough to further prevent fluid from escaping out the top end of the cannula whether an instrument is present in the cannula or not in order to protect the abdominal cavity.

Haber et al. also disclose each seal segment having a circumference of 180 degrees but does not expressly disclose the segments having a circumference greater than 180 degrees, although Haber et al. disclose that instead of four sealing elements having a circumference of 180 degrees, three sealing elements may be used which may necessitate the segments to have a circumference of more than 180 degrees (col. 7, lines 63-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made for the seal segments to have a circumference greater than 180 degrees, since it has been held that where the general conditions of a claim

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are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

In addition, Haber et al. disclose a (“conical”) valve **136** within the housing disposed distally of and spaced from the instrument seal being operable to provide a seal in absence of an instrument positioned through the housing (Figure 4; col. 2, lines 3-21), except for the valve being zero closure, although Haber et al. acknowledges the need for tighter valves seal against smaller diameter instruments (col. 3, lines 1-21).

Honkanen et al. teach the seal further providing a zero-closure valve (Figure 5). It would have been obvious to one of ordinary skill in the art to modify Haber et al. by providing a zero-closure valve, as taught by Honkanen et al., in order to further form a tighter seal that would allow a snug fit about the instrument and to prevent fluid from escaping out the top end of the cannula (col. 4, lines 45-52).

Claims 2 and 10: Haber et al. disclose the claimed device, except for the plurality of layered elastomeric members forming a non-planar shape.

Honkanen teaches a cannula with a non-planar-shaped seal **55** (Figure 4). Honkanen teaches that the non-planar or conical shape assists in the formation of a tight seal about an instrument being inserted into the cannula since fluid pressure will cause the non-planar seal member to collapse into the instrument and cause it to adhere more securely thereto (col. 4, lines 53-58). It would have been obvious to one of ordinary skill in the art at the time of invention to provide non-planar-shaped elastomeric members, as taught by Honkanen, to Haber in order to further facilitate a secure

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adhesion to the inserted instrument and to provide a shape that contacts more surface area of the instrument.

Claims 3, 11, and 19: Haber discloses the claimed device except for the elastomeric members comprising a proximal flange portion and an inwardly extending portion extending distally therefrom, wherein said proximal flange portions are disposed between and are abutting against said rings.

Honkanen teaches a proximal flange portion **56** and an inwardly extending portion **58**, wherein said proximal flange portions which would be disposed between and are abutting against the rings in the device of Haber (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a proximal flange portion and an inwardly extending portion, as taught by Honkanen, to Haber since it was known in the art that seals with such portions are more securely mounted to the valve housing and more efficiently seal instruments that move through the valve.

3. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Haber et al.** (U.S. Patent No. **5,385,552**) in view of **Honkanen et al.** (U.S. Patent No. **4,655,752**), as applied to claim 1 above, and further in view of **Hart et al.** (U.S. Patent No. **5,385,553**)

Claim 4: Haber et al. and Honkanen et al. disclose the claimed device except for the seal assembly having an outer perimeter which is attached to a flotation means.

Hart et al. teach the seal assembly having an outer perimeter which is attached to a flotation means **39** that allows for movement of the septum orifice to an off-axis

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position without deformation (Figure 12, col. 2, lines 6-18 and col. 10, lines 41-63). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Haber et al. and Honkanen et al. by providing a flotation means being attached to the outer perimeter of the seal assembly, as taught by Hart et al., in order to prevent deformation of the septum orifice.

Claim 5: Haber et al. and Honkanen et al. disclose the claimed device except for the seal assembly including a plurality of protectors disposed proximal to said elastomeric seal.

Hart et al. teach seal assembly including a plurality of protectors that comprises outer leaves **105**, **107** and inner leaves **125**, **127** disposed proximal to said elastomeric seal (Figures 9-10, col. 6, lines 48-68). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a plurality of protectors proximal to elastomeric seal, as taught by Hart et al., to Haber et al. and Honkanen et al. in order to shield the sealing members from the pushing force of the instruments.

4. Claims 17 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Haber et al.** (U.S. Patent No. **5,385,552**).

Haber et al. disclose a trocar **2** with a hollow cannula **32** having a distal end and proximal end and a valve housing **58** attached to the proximal end of the cannula, wherein the proximal end has a wall attached thereto having an aperture therethrough, and an instrument seal assembly **122** disposed within said housing comprising a first substantially rigid ring **132**, and a second substantially rigid ring **134** and a plurality of

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layered elastomeric members, or four separate semicircular seal segments **126**, compressed therebetween, each having a circumference of 180 degrees, and arranged circumferentially about an aperture in an alternating over and under pattern in a non-planar shape (the elastomeric members also have a non-planar shape prior to being assembled together), and circumscribing an aperture in an interwoven pattern and cooperating to seal against objects positioned within the aperture, and each seal segment has a starting edge facing in the same circumferential direction and an ending edge facing in the opposite circumferential direction wherein the starting edge of each seal segment overlaps and is positioned on top of the ending edge of the adjacent seal segment, and the seal segments cooperate to seal against objects or instruments positioned within the aperture (Figures 2 and 5A).

Haber et al. do not expressly disclose each seal segment **126** being gas-tight or sufficiently sealing against instruments positioned through the seal to maintain gas pressure in the abdominal cavity during endoscopic surgical procedures, however discloses having good sealing qualities (col. 2, lines 11-44). It would have occurred to one of ordinary skill in the art to form a seal tight enough that would further prevent fluid from escaping out the top end of the cannula whether an instrument is present in the cannula or not in order to protect the abdominal cavity.

Haber et al. also disclose each seal segment having a circumference of 180 degrees but does not expressly disclose the segments having a circumference greater than 180 degrees, although Haber et al. disclose that instead of four sealing elements having a circumference of 180 degrees, three sealing elements may be used which may

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necessitate the segments to have a circumference of more than 180 degrees (col. 7, lines 63-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made for the seal segments to have a circumference greater than 180 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Response to Arguments

5. Applicant's arguments filed 11/30/2009 have been fully considered but they are not persuasive.

6. Applicant generally argues that Haber et al. do not disclose the plurality of layered elastomeric members **122** being "arranged about an aperture" since it seals the path within the device when no instrument is positioned, and therefore would not have an aperture which would cause leakage. The examiner disagrees. The claim recitation of being "arranged about an aperture" is not the same as forming an aperture. All that is necessitated by the claims is that the members be arranged or circumscribed around an aperture, which may include the apertures formed by the rings **132** or **134** or even the central aperture formed when an instrument is disposed through device, such as in Figure 3A. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims, and therefore the device of Haber et al. read on this limitation.

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7. Applicant also argues that the members **122** of Haber et al. do not seal against instruments positioned within the aperture, but rather conical valve **136** provides sealing, and that modifying the members **122** to sufficiently seal to maintain gas pressure in the abdominal cavity would not be proper since there is no motivation. However, Haber et al. disclose a seal which comprises *both* a proximal seal **122** and a distal conical valve seal **136**, wherein the seal “seals the path both when the obturator or any surgical device is within the trocar body and once the obturator/surgical device has been removed from the trocar body” (col. 2, lines 4-32). Both seals engage an inserted instrument, as disclosed in Figure 3A, and therefore seal against the instrument to some extent. Haber et al. do not expressly disclose to what extent the seal seals against the instruments, but a modification to provide the seal **122** to maintain gas pressure in the abdominal cavity would have been obvious to further seal the device to protect the abdominal cavity.

8. Applicant argues that modifying the plurality of layered elastomeric members to form a non-planar shape would not have been obvious. However, the examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of invention to provide non-planar-shaped elastomeric members, as taught by Honkanen et al., to Haber et al. in order to further facilitate a secure adhesion to the inserted instrument and to provide a shape that contacts more surface area of the instrument.

9. In regards to applicant’s request to specifically point out where the seal elements of the plurality of layered elastomeric members are arranged around an aperture as a non-final rejection to provide applicant with a full and fair opportunity to respond would

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be improper, since doing so would be only be proper if a new grounds of rejection was set forth by the examiner that was not necessitated by applicant's amendment, or if the applicant's arguments are persuasive, neither of which is the case.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DIANE YABUT** whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734